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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,779	09/23/2004	Yoshihiko Masaki	40072-0011	8473

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EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/508,779	MASAKI ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 31 October 2007 has been entered.

Status of Claims

Claims 1-4 and 6-11 are pending, and are thus examined herein on the merits for patentability. No claim is allowed at this time.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-4 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 08-034701 (Akiyo et al.), as evidenced by Bussière et al., J. Chem. Biol., 2001, 130(4): 561-568 (Bussière et al.).

Applicant claims:

Applicants claim a composition comprising 3.5-300 g/L inulin type fructan, 5-150 mM Na^+, 5-150 mM K^+, and 10-150 mM of at least one of Cl^-, $HCO3^-$, CO_3^{2-}, organic acids, and organic acid anions. Claims 2-4 limit the inulin type fructan to a degree of polymerization of 3 to 6, preferably 1-kestose or nystose. Claim 6 further comprises 0-20 mM Mg^2+, 0-5 mM Ca^{2+}, 0-150 mM $H_2PO_4^-$ and /or HPO_4^{2-}, and 1-100 g/L hydroxyethyl starch. Claims 8-9 are drawn to a method for preserving an organ comprising perfusing said organ with the composition of claim 1. Claims 10-11 are drawn to a method for suppressing hypofunction of and damage to an organ (i.e. kidney, liver, heart, lung or pancreas) during an organ transplantation process, or improving hypofunction of an organ during an organ transplantation process via contacting said organ with the composition of claim 1.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Akiyo et al. teach a method for maintaining the properties and functions of an organ (i.e. liver or kidney) on the cellular level by perfusing said organ with a

composition comprising a sugar liquid such as mannitol or inulin (Abstract; claims 1-3, 23-26 and 31-34; and paragraphs [0003]-[0004] and [0009]). Akiyo et al. further teach an example wherein the sugar liquid comprises 1 g D-mannitol and 20 ml Krebs-Ringer buffer solution (paragraph [0025]). Krebs-Ringer buffer solution comprises124 mM NaCl, 5.0 mM KCl, 1.5 mM $CaCl_2$, 1.3 mM $MgCl_2$, 20 mM NaOH, and 10 mM glucose at pH 7.4, as evidenced by Bussière et al. (page 563, left column, lines 26-28).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Akiyo et al. do not explicitly teach a perfusion composition comprising 3.5-300 g/L of an inulin, 5-150 mM Na^+, 5-150 mM K^+, and 10-150 mM of at least one of Cl^-, $HCO3^-$, CO_3^{2-}, organic acids, and organic acid anions, as in instant claim 1. However, Akiyo et al. clearly teach that inulin and mannitol are functionally equivalent sugars for perfusion of organs (claims 2-3, 25-26 and 33-34; and paragraph [0009]).

It is noted that Akiyo et al. do not teach the inulin to comprise 1-kestose or nystose. However, inulin refers to polymers consisting of fructose units joined by a β-(2-1) glycosidic bond that typically have a terminal glucose. Thus, 1-kestose and nystose are encompassed by the teaching of inulin.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to substitute inulin for mannitol in the perfusion composition

comprising mannitol and Krebs-Ringer buffer solution because mannitol and inulin functionally equivalent, as reasonably suggested by Akiyo et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claims 1-2, 4 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,306,508 (hereinafter Kossovsky et al.), in view of U.S. Patent No. 4,879,283 (hereinafter Belzer et al.).

Applicant claims:

Applicants claim a composition comprising 3.5-300 g/L inulin type fructan, 5-150 mM Na^+, 5-150 mM K^+, and 10-150 mM of at least one of Cl^-, $HCO3^-$, CO_3^{2-}, organic acids, and organic acid anions. Claims 2and 4 limit the inulin type fructan to a degree of polymerization of 3 to 6, preferably nystose. Claim 6 further comprises 0-20 mM Mg^2+, 0-5 mM Ca^{2+}, 0-150 mM $H_2PO_4^-$ and /or HPO_4^{2-}, and 1-100 g/L hydroxyethyl starch. Claims 8-9 are drawn to a method for preserving an organ comprising perfusing said organ with the composition of claim 1. Claims 10-11 are drawn to a method for suppressing hypofunction of and damage to an organ (i.e. kidney, liver, heart, lung or pancreas) during an organ transplantation process, or improving hypofunction of an

organ during an organ transplantation process via contacting said organ with the composition of claim 1.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Kossovsky et al. teach a red blood cell surrogate comprising nanocrystalline core particles which are coated with an oxygen carrier anchor (column 3, lines 11-14). Kossovsky et al. teach that the red blood cell surrogates are suitable for *in vitro* perfusion of organs such as hearts, livers and kidneys during transport and storage prior to transplantation. Kossovsky et al. further teach that the red blood cell surrogates may be reconstituted with any of the well known aqueous pharmaceutical carriers, such as buffered saline, with or without allosteric effectors, plasma and whole blood (column 5, lines 62-67).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Kossovsky et al. do not explicitly teach an example wherein nystose is the oxygen carrier anchor located on the surface of said nanocrystalline core particle. However, Kossovsky et al. clearly teach that nystose is a suitable oxygen carrier anchor (column 4, lines 37-39; and claims 1-3).

Also, Kossovsky et al. do not teach the aqueous pharmaceutical carriers to comprise the instantly claimed ranges of Na^+, K^+, and at least one of Cl^-, HCO_3^-, CO_3^{2-}, organic acids, and organic acid anions. However, Belzer et al. teach that Collins solution, or the modified EuroCollins solution is preferred by most transplant centers

that preserve kidneys by cold-storage (column 2, lines 35-38). The instant specification teaches that EuroCollins solution comprises 10 mM Na^+, 115 mM K^+, 15 mM Cl^-, 10 mM HCO_3^-, 15 mM $H_2PO_4^-$, and 42.5 mM HPO_4^{2-} (Example 1).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use nystose as the oxygen carrier anchor of Kossovsky et al. along with a solution of EuroCollins solution, as reasonably taught by Belzer et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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